

California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814-6237 Phone (916) 445-5014 Fax (916) 327-6308 Website - www.pharmacy.ca.gov STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

REQUIREMENTS FOR FILING AN APPLICATION FOR STERILE COMPOUNDING PHARMACY LICENSE

(Business & Professions Code Sections 4127 and 4127.1)

Effective July 1, 2003, a pharmacy may not compound injectable sterile drug products in California unless:

- 1. The pharmacy is specially licensed with the board as a sterile compounding pharmacy, OR:
- 2. The pharmacy is operated by an entity that is licensed by the board or the State Department of Health Services and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board (at the current time there is no other agency)

Nevertheless <u>all</u> pharmacies that compound injectable sterile drug products must follow board regulations for sterile compounding. These regulations are found in Title 16 of the California Code of Regulations as Article 8, beginning with section 1751.

Note: If a nonresident pharmacy is shipping injectable sterile drug products into California, the pharmacy must also comply with board regulations for sterile compounding. It also must be separately licensed by the board to compound injectable sterile drug products, unless it is operated by an entity that is licensed by the board or the State Department of Health Services and has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or another accreditation agency approved by the board (at the current time there is no other agency). A separate application form for nonresident pharmacies is required and can be obtained from the board's Web site.

A license to compound injectable sterile drug products may only be issued to the owner of a licensed pharmacy at the licensed location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found to be in compliance with Article 7.5 of Chapter 9, of Division 2 of the Business and Professions Code and regulations adopted by the board.

For a complete application, the following items must be submitted:

- 1. A completed and signed Application for Sterile Compounding Pharmacy License (17A-48).
- 2. Fee of \$500, made payable to "Board of Pharmacy"
- 3. A copy of the pharmacy's proposed policies and procedures for sterile compounding on disk, CD, or via email. If emailing the policies and procedures, please send to CompoundingPharmacy@dca.ca.gov.

4. Corporate officer, owner, or partner who signed the application will need to complete the enclosed "Request for Live Scan Service" form.

Fingerprint Requirements

California Residents

The board will only accept Live Scan Service Forms from California residents.

Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the Instructions for completing a "Request for Live Scan Service" form. Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice website at http://caag.state.ca.us/app/contact.pdf or the sources listed on the bottom of the instructions for completing a "Request for Live Scan Service" form.

The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach the second copy of the form to your application and submit to the board.

Non California Residents

If an owner, partner, corporate officer, major shareholder or director reside out of state they must submit rolled fingerprints on cards provided by the board and include a separate fee of \$42 (\$32 California Department of Justice (DOJ) processing fee and \$10 DOJ expedite fee). (Live Scan processing fees are paid directly at the Live Scan site.) You may contact the board to request fingerprint cards at (916) 445-5014. You may also request cards on our website at www.pharmacy.ca.gov.

Fingerprints submitted on cards should be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take approximately six weeks (live scan is faster). Poor quality prints may result in rejection and will substantially delay licensing as additional fingerprint cards will be required from you for processing.

The board will only accept fingerprint cards from residents outside of California.



California State Board of Pharmacy 400 R Street, Suite 4070, Sacramento, CA 95814-6237 Phone (916) 445-5014 Fax (916) 327-6308 www.pharmacv.ca.gov

STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

APPLICATION FOR A STERILE COMPOUNDING PHARMACY LICENSE

Please print or type ALL BLANKS MUS	ST BE COMPLETED; IF NOT APPLICAE	SLE, ENTER N/A		
Name of Pharmacy:		Pharmacy License	Number	
Pharmacy Telephone Number: Sterile Compounding Telephone Number: (if different)				
Address of Pharmacy: Street and	Number City	State	Zip Code	
Name of pharmacist-in-charge of licensed pharmacy: Pharmacist license number				
Residence address: Street and	Number City	State	Zip Code	
Indicate whether this application is for:				
New Licensed Sterile Change of Location of Licensed Compounding License Sterile Compounding pharmacy Sterile Compounding pharmacy				
If this is a change of ownership or change of location , indicate previous name, address and license number of compounding pharmacy.				
Name:	Address:		License Number:	
Please indicate type of ownership:				
Individual Partnership	Corporation Not-for-profi	t corporation	Government owned	
I certify that the policies and procedures of the sterile compounding are consistent with California Code of				
Regulations Title 16, section 1751 et seq. (Please include electronic version of procedures with this application)				
regulations rate re, occurrer or or or or or an include electronic version of procedures with the application)				
Signature of Pharmacist-in-Charge Name (please print) Date			Date	
CONTINUE ON REVERSE				
FOR OFFICE USE ONLY				
STAFF REVIEW CASHIER LOG				
oo	Approved	Cashier #		
oo	Denied	Date		
Referred for inspection:				
Inspection Completed:	Date	Amount of fe	e	

Ownership Information

If a Sole (Ownership:						
Name of So			*Social Security Num	nber	Telephone	Number	
Address	number and street	City	State Zip Code				
If a Partn	ership: (attach additional sheet if nee	eded)					
Name of Pa			*FEIN Number		Telephone	Number	
Address	number and street	City		State	Zip Co	ode	
Name of Pa	artner		*FEIN Number		Telephone	Number	
Address	number and street	City	State Zip Code				
If a Corpo	oration: (attach additional sheet if ne	eded)					
	orporation (If applicable)	,			Telephone	Number	
Address	number and street	City		State	Zip C	ode	
partners, on pharmacis	w the name, title, address and lice corporate officers. Under the head st, physician, podiatrist, dentist or additional titles of persons holding corporate	ling "Licensed as" veterinarian etc., a	list any state profess nd license number.	sional or vocat Non-profit org	ional licens	es held; e	.g.,
Title	Name	Residence Address Social Secur Number		-			
mandatory collection purposes you fail to AND you	re of your social security number (v. Section 30 of the Business and of your social security number. Your compliance with any judgment of disclose your social security number may be reported to the Franchise.	Professions Code our social security or order for family ber or your FEIN, y	e and Public Law 94- number or FEIN will support in accordan our application for i	455 (42 USCA be used excluded the with section or renewall the with section or renewall the with the w	A 405(c)(2)(usively for to a 17520 of to al license w	C)) autho ax enforce he Family	rize ement Code. If
*Federal	Employer Identification Number						

PLEASE READ CAREFULLY

This application must be approved by the California State Board of Pharmacy before a Sterile Compounding License will be issued.

If changes are made during the application process, you may need to submit a new application with the appropriate fees. Any application not completed within 60 days after you have been notified by the board of deficiencies in your file, may be deemed to have been abandoned, and you may be required to file a new application and meet all the requirements which are in effect at the time of application. Fees applied to this application are not transferable and are not refundable.

Any material misrepresentation in the answer of any question is grounds for refusal or subsequent revocation of a license, and is a violation of the Penal Code of California. All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete.

The information will be used to determine qualifications for licensure under California Pharmacy Law. The officer responsible for information maintenance is the Executive Officer, (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814. The information may be transferred to another governmental agency (such as a law enforcement agency) if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on him/her by the Board of Pharmacy, unless the records are identified as confidential information and exempted from disclosure by the California Information Practices Act. (Civil Code §1798, et seg.)

Under penalty of perjury, under the laws of the State of California, the person whose signature appears below, certifies that: (1) he/she is the owner or an officer of the applicant corporation named in the foregoing application, duly authorized to make this application on its behalf <u>and</u> is at least 18 years of age; (2) he/she has read the foregoing application and knows the contents thereof and that all statements therein made are true; (3) no person other than the applicant has any direct or indirect interest in the applicant's business to be conducted under the license(s) for which this application is made; (4) all supplemental statements are true and accurate; I am also aware that I am bound by the applicable federal and state laws and regulations pertaining to the practice of pharmacy.

Signature of corporate officer, owner, or partner	Name (please print)	Title	Date
Mail all correspondence to the following address below. "Same as Pharmacy."	If correspondence should be mail	ed to the phar	macy please insert
Name and telephone number of contact person to clarify application.	information provided on this	e-mail addr	ess

INSTRUCTIONS FOR COMPLETING A "REQUEST FOR LIVE SCAN SERVICE" FORM

(California Residents)

The following instructions are provided to assist you in completing this form accurately. Please follow all instructions carefully and print clearly; failure to do so may result in processing delays of your application.

- 1. Job Title or Type of License, Certification, or Permit: Enter the type of license, certification or permit for which you are applying. Appropriate license types include pharmacist, pharmacy technician, intern pharmacist, exemptee, or if an owner or officer of a pharmacy, hospital, clinic, wholesaler or hypodermic permit enter appropriate title of the facility.
- 2. Name of Applicant: Enter your last name, first name and middle name. Do not use initials or name abbreviations.
- **3. AKA:** Enter all other names you have used, including your maiden name.
- 4. CDL No: Your California Driver's License Number.
- 5. DOB: Your date of birth (month/day/year).
- 6. SEX: Your gender (male or female).
- 7. HT: Your height in feet and inches.
- 8. WT: Your weight in pounds.
- **9. Misc. No.:** Enter other identifying numbers. (e.g., Other State Driver's License Number)
- 10. EYE Color: Color of your eyes
- 11. HAIR Color: Color of your hair
- 12. Home Address: Your residence address
- **13. POB:** Enter your place of birth.
- 14. SOC: Enter your Social Security Number

Take the completed form to your nearest Live Scan site for fingerprint scanning. There are more than 130 Live Scan sites throughout the state. An up-to-date Live Scan site list is on the Department of Justice's (DOJ) Internet web page at http://caag.state.ca.us/app/contact.pdf or call your local police or sheriff's department.

Contact the live scan service for hours of operation, an appointment (if necessary), acceptable forms of payment and identification requirements. Be prepared to pay **ALL applicable fees** (the DOJ processing fee of \$32 and fingerprint scanning service fee) at the time your prints are taken. The live scan fingerprinting service fee varies from about \$5 to \$20. The cost to electronically submit your fingerprints is determined by the local Live Scan agency and the agency can charge a fee sufficient to recover its costs.

The lower portion of the Request for Live Scan Service form must be completed by the live scan operator. The original of the form is retained by the scanning service; the second copy is to be attached to your application and submitted to the board; and the third copy is for your records.

FINGERPRINTING AUTHORITY

Section 144(b) of the Business and Professions Code authorizes the Board of Pharmacy to require an applicant for licensure to furnish a full set of fingerprints for purposes of conducting criminal history record checks. Fingerprints are required in order for the DOJ to conduct background checks for criminal convictions.

REQUEST FOR LIVE SCAN SERVICE

Applicant Submission

ORI: Code assigned by DOJ Job Title or Type of License, Certification or Permit:	Employment License, Certification, Permit Volunteer
Agency Address Set Contributing Agency:	
Agency authorized to receive criminal history information	Mail Code (five-digit code assigned by DOJ)
Street No. Street or PO Box	Contact Name (Mandatory for all school submissions)
City State Zip 0	Code Contact Telephone No.
Ofty State Lip.	Coule Contact relephone No.
Name of Applicant:	First Middle
AKA's:	CDL No
DOB: SEX: Male Female	Misc. No. BIL - Agency Billing Number (if applicable)
HT: WT:	Misc. No
EYE Color: ———— HAIR Color: ————	Home Address:
POB:	Street or PO Box
SOC:	City, State and Zip Code
Your Number: OCA No. (Agency Identifying No.) If resubmission, list Original ATI No.	Level of Service DOJ FBI
Employer: (Additional response for Department of Social Services, I	DMV/CHP licensing, and Department of Corporations submissions only)
Employer Name	
Street No. Street or PO Box	Mail Code (five digit code assigned by DOJ)
City State Zip (Code Agency Telephone No. (Optional)
Live Scan Transaction Completed By: Name of Operation	Date
Transmitting Agency ATI	No. Amount Collected/Billed

REQUEST FOR LIVE SCAN SERVICE

Applicant Submission

ORI: Code assigned by DOJ Job Title or Type of License, Certification or Permit:	Employment License, Certification, Permit Volunteer
Agency Address Set Contributing Agency:	
Agency authorized to receive criminal history information	Mail Code (five-digit code assigned by DOJ)
Street No. Street or PO Box	Contact Name (Mandatory for all school submissions)
City State Zip 0	Code Contact Telephone No.
Ofty State Lip.	Coule Contact relephone No.
Name of Applicant:	First Middle
AKA's:	CDL No
DOB: SEX: Male Female	Misc. No. BIL - Agency Billing Number (if applicable)
HT: WT:	Misc. No
EYE Color: ———— HAIR Color: ————	Home Address:
POB:	Street or PO Box
SOC:	City, State and Zip Code
Your Number: OCA No. (Agency Identifying No.) If resubmission, list Original ATI No.	Level of Service DOJ FBI
Employer: (Additional response for Department of Social Services, I	DMV/CHP licensing, and Department of Corporations submissions only)
Employer Name	
Street No. Street or PO Box	Mail Code (five digit code assigned by DOJ)
City State Zip (Code Agency Telephone No. (Optional)
Live Scan Transaction Completed By: Name of Operation	Date
Transmitting Agency ATI	No. Amount Collected/Billed

REQUEST FOR LIVE SCAN SERVICE

Applicant Submission

ORI: Code assigned by DOJ Job Title or Type of License, Certification or Permit:	Employment License, Certification, Permit Volunteer
Agency Address Set Contributing Agency:	
Agency authorized to receive criminal history information	Mail Code (five-digit code assigned by DOJ)
Street No. Street or PO Box	Contact Name (Mandatory for all school submissions)
City State Zip 0	Code Contact Telephone No.
Ofty State Lip.	Coule Contact relephone No.
Name of Applicant:	First Middle
AKA's:	CDL No
DOB: SEX: Male Female	Misc. No. BIL - Agency Billing Number (if applicable)
HT: WT:	Misc. No
EYE Color: ———— HAIR Color: ————	Home Address:
POB:	Street or PO Box
SOC:	City, State and Zip Code
Your Number: OCA No. (Agency Identifying No.) If resubmission, list Original ATI No.	Level of Service DOJ FBI
Employer: (Additional response for Department of Social Services, I	DMV/CHP licensing, and Department of Corporations submissions only)
Employer Name	
Street No. Street or PO Box	Mail Code (five digit code assigned by DOJ)
City State Zip (Code Agency Telephone No. (Optional)
Live Scan Transaction Completed By: Name of Operation	Date
Transmitting Agency ATI	No. Amount Collected/Billed